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IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF UTAH, CENTRAL DIVISION

THORNE RESEARCH, INC. and SOFTGEL FORMULATORS, INC., Plaintiffs, vs. ATLANTIC PRO-NUTRIENTS, INC. d/b/a/ XYMOGEN, Defendant	Case No. 2:13-cv-00784-TS-PMW **PLAINTIFFS' RESPONSE TO XYMOGEN'S OPENING CLAIM CONSTRUCTION BRIEF** Judge Ted Stewart Magistrate Judge Paul M. Warner

Pursuant to the Court's Scheduling Order and L.P.R. 4.2, Plaintiffs Thorne Research, Inc. ("Thorne") and Softgel Formulators, Inc. ("SFI"), (collectively, "Thorne") submit their Response to Xymogen's Opening Claim Construction Brief (Dkt. No. 55.

INTRODUCTION

While Xymogen purports to propose a "plain meaning" (or ordinary meaning) construction for "non-crystalline" as "lacking crystals" (Dkt. No. 55 at p. 10-11), the express text of the specification demonstrates that the patentee ascribed a special definition to that term in the context of the claimed composition. As set forth herein, that definition provides clear notice of claim scope (unlike Xymogen's) and is further supported by the extrinsic evidence, including Xymogen's own statements about its products.

Xymogen also states that its proposed construction of "carrier oil" "simply seeks to specify what the oil is carrying and where the oil is carrying its cargo to." Dkt. No. 55 at p. 6. However, as appreciated from Thorne's Motion for Claim Construction, and as further explained herein, the effect of the composition on the human body is a less appropriate basis for interpreting the claimed composition than the carrier oil's effect on that composition. It follows that Thorne proposes a construction for "carrier oil" that focuses on the claimed CoQ10 composition itself, in contrast to Xymogen's construction. Indeed, Xymogen's "human effect" construction is unsupported by the specification and ignores the criticality of Thorne's construction related to increasing volume of the CoQ10 dosage.

ARGUMENT

I. Xymogen's Proposed Constructions of "Non-Crystalline" and "Carrier Oil" Are Unsupported and Should Be Construed as Proposed by Thorne.

A. Xymogen's Proposed Construction of "Non-Crystalline" Ignores the Inventor's Special Definition and Xymogen's Own Extrinsic Evidence.

The parties proposed the following claim constructions for the term "non-crystalline":

Thorne	Xymogen
lacking crystals visible by light microscope at magnifications of 640x.	lacking crystals.

(1) "Non-Crystalline" has a Special Definition in the Specification.

"The construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be, in the end, the correct construction." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1316 (Fed. Cir. 2005) (citing *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1250 (Fed. Cir. 1998). "Consistent with that general principle, our cases recognize that the specification may reveal a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess. In such cases, the inventor's

lexicography governs." *Phillips* at 1316 (citing *CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1366 (Fed. Cir. 2002).

The '888 patent states the "present invention relates to a crystal-free absorbable CoQ10 wherein no CoQ10 crystals are visible by light microscope at magnifications of 640x." Col. 2, lines 30-33. Xymogen alleges that "restricting the construction of non-crystalline to that technique is not consonant with the plain meaning of the word [non-crystalline]." Dkt. No. 55 at p. 11. Contrary to Xymogen's assertion, the proposed construction is indeed consonant with the plain meaning in that both define "non-crystalline" to mean "lacking crystals." The specification appropriately supplements the plain meaning with a special definition providing a clearer notice to the public regarding when a composition should be considered to lack crystals and when it should not. Xymogen's construction, to the contrary, provides the public with virtually no notice in that regard and, as such, is too generic to lend any meaning to the claim.

(2) Extrinsic Evidence Further Supports this Special Definition.

Extrinsic evidence in the form of Xymogen's own product labels and a technical study commissioned by its product manufacturer further support Thorne's proposed definition. "The court may, in its discretion, receive extrinsic evidence in order 'to aid the court in coming to a correct conclusion' as to the 'true meaning of the language employed' in the patent." *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 980 (Fed. Cir. 1995), quoting *Seymour v. Osborne*, 78 U.S. (11 Wall.) 516, 546, 20 L.Ed. 33 (1871).

Here, Xymogen's own product labels affixed to the accused products advertise "Crystal-Free CoQ10." Exh. A. In support of its crystal-free claim, Xymogen's data sheet for the CoQmax CF product states that the CF and 100 CF products are "crystal-free when examined by a light microscope." *See* Exh. 1 to the Declaration of James Lake to this Opposition ("Lake Decl.") While the data sheet does not specify magnification power, Xymogen's product

manufacturer, National Vitamin Co., commissioned a technical study to determine whether a particular product containing coenzyme Q10 contained crystals. Exh. B, at p. 3. The research laboratory's method of determining the presence of crystals included looking through a light reflection microscope at a magnification level similar to 640x, as well as other lower levels of magnification. Thus, it appears that Xymogen's manufacturer of the accused product considers a composition to be "crystal-free" under the same conditions as the definition proposed by Thorne.

Furthermore, the referenced study commissioned by National Vitamin refers to Formula D, a composition which contains CoQ10. Formula D exhibits the same maximum concentration (Cmax, ug/ml) and total absorption (ug) for CoQ10 as the data sheet for CoQmax indicates that CoQmax CF and 100-CF have. *Compare* Exh. B, p. 7; Exh. 1 to the Lake Decl., Figures 1 and 3. This strongly suggests that the National Vitamin study provided the technical basis for the absorption data shown in the Xymogen data sheet. Therefore, when Xymogen claims that its coQmax CF and coQmax 100 CF products are "crystal-free," on their labels and in the coQmax CF data sheet, this is likely based on their products having been examined by a light microscope at a magnification power similar to 640x, as reported in the National Vitamin study.

Accordingly, Thorne proposes to construe "non-crystalline" under a more stringent magnification at 640x. Xymogen seeks to avoid a construction based on a standard closely similar to the standard supporting Xymogen's own crystal-free claims.

(3) The Prosecution History Cited by Xymogen Is Not Determinative.

Despite the foregoing, Xymogen contends that "restricting the construction of non-crystalline to that technique is not consonant … with the file history." Dkt. No. 55 at p. 11. Specifically, Xymogen refers to an examiner statement that "crystal-free" and "non-crystalline" are "absolute limitations barring crystals from the composition," referring to cancelled claim 5 reciting "coenzyme Q10 is essentially crystal-free." *Id.* Xymogen also refers to the Patentee's

attempt to distinguish Udel in responding to a different rejection, arguing that "the Udel patent does not disclose a complete lack of crystals, as claimed in the instant claims." *Id.*

Since "the prosecution history represents an ongoing negotiation between the PTO and the applicant, rather than the final product of that negotiation, it often lacks the clarity of the specification and thus is less useful for claim construction purposes." *Phillips v. AWH Corp.* at 1317 (citations omitted). The lack of clarity quickly appears in the '888 prosecution history upon review beyond the cited quotations. Significant claim amendments were made compared to the claims addressed in the cited quotations, such that the allowed claims were much different than those claims. Furthermore, and critically, Thorne's proposed construction is not inconsistent with the cited quotations. Thorne has not proposed to add crystalline CoQ10 to the list of claimed ingredients, as was done in cancelled claim 5. Instead, the proposed construction merely defines the standard for identification of whether crystals are present.

B. Xymogen's Proposed Construction of "Carrier Oil" Is Inappropriate in the Context of a Composition Claim and Unsupported by the Specification and Prosecution History.

The parties proposed the following claim constructions for the term "carrier oil":

Thorne	**Xymogen**
an oil that increase the volume of an individual dosage of CoQ10 delivered into the intestines of the human taking the present invention, which increases the overall surface area from which the CoQ10 can be absorbed.	an oil that carries CoQ10 molecules [in the passive facilitative diffusion process][1] across absorptive cells in the intestine.

[1] This phrase is bracketed because Xymogen offered the construction of "an oil that carries CoQ10 molecules across adsorptive [sic] cells in the intestine" as an alternative construction in footnote 2 of its Brief. Dkt. No. 55.

(1) The Portion of the Specification Relied Upon by Thorne Provides Appropriate Context for the Composition Claims.

Xymogen and Thorne agree that "carrier oil" should be defined as an oil. Dkt. No. 55 at p. 8-9. The '888 patent states that the "lipid carrier increases the volume of an individual dosage of CoQ10 delivered into the intestines of the human taking the present invention, which increases the overall surface area from which the CoQ10 can be absorbed." Col. 3, lines 4-9. As noted in Thorne's Motion for Claim Construction, although the referenced text mentions "lipid carrier" instead of "carrier oil," context demonstrates that lipid carrier means the same thing as carrier oil in the '888 patent. Dkt. No. 54 at p. 6. Furthermore, consistent with usage in the '888 patent, "overall surface area from which the CoQ10 can be absorbed" should be understood to refer to "overall surface area [of the dosage]."[2]

The sentence from the specification relied upon by Thorne uniquely describes the carrier oil's ***effect*** on the CoQ10 ***composition***; namely, increasing the volume of the CoQ10 dosage (which increases the dosage's surface area). In the context of a composition claim, it is appropriate to define this term with reference to the ingredients of the claimed composition, not their effect on humans. Determining whether adding a specific oil to a substance increases the volume of the substance can be readily determined without significant experimentation.

In contrast, by seeking to define this term based on how a carrier oil functions in the human body, Xymogen's proposed construction runs afoul of the principle that patents must provide the public with notice of what the patent covers. *Superior Fireplace Co v. Majestic Prods.*, 270 F.3d 1358, 1371 (Fed. Cir. 2001) ("The public is entitled to rely upon the public

[2] The paragraph discussing carrier oils in the '888 patent lists various examples of carrier oils, but it is clear that the invention is not limited to those specific examples. One thing all the examples have in common is that adding them will increase the volume of the dosage.

record of a patent in determining the scope of the patent's claims. . . . Both the Supreme Court and this court have highlighted the importance of the notice function of patent claims."). Xymogen's proposed definition of carrier oil as "an oil that carries CoQ10 molecules in the passive facilitative diffusion process across absorptive cells in the intestine" (Dkt. No. 55 at p. 6) necessarily implicates knowledge regarding how a particular ingredient functions inside the body. Unless that information is somehow readily accessible, which Xymogen has not shown and cannot show, a description of how the carrier oil functions in the human body read into the term "carrier oil" would require a great deal of experimentation to determine whether a particular ingredient infringes the patent.

Xymogen's construction is inappropriate for the additional reason that it attempts to read the function of ***how*** a material might perform its tasks in the human body into the claims. Courts have repeatedly held that a patentee need not "understand or be able to state the scientific principles underlying his invention." *Diamond Rubber Co. v. Consolidated Rubber Tire Co.*, 220 U.S. 428, 435-36, 31 S.Ct. 444, 55 L.Ed. 527 (1911). As long as the patentee sufficiently discloses the invention, he need not understand *how* it actually works. *Id.* And, to the extent that the inventor of the '888 patent has set forth a theory of ***how*** CoQ10 may be absorbed from the gut into the body, this is irrelevant to the patent's claims. Courts will ignore a patentee's misunderstanding of ***how*** the patented invention actually functions even when the patentee himself put the patentee's theory of how it works into the claims, as long as the actual invention is disclosed. *See, e.g.*, *Heltra, Inc. v. Richen-Gemco, Inc.*, 494 F.Supp. 12, 17 (D.S.C. 1979) (quoting *Aerosole Research Co. v. Scovill Mfg. Co.*, 137 U.S.P.Q. 701 (N.D.Ill.1963)) (affirmed *Heltra, Inc. v. Richen-Gemco, Inc.*, 631 F.2d 728 (4th Cir. 1980)("A mistake in theory and functionality of structure recited in the specification or in the claims is not fatal to the validity of

the claims."); *see also, e.g.*, *Katz v. Horni Signal Mfg Corp.*, 145 F.2d 961, 963, 63 U.S.P.Q. 190 (2nd Cir. 1944) ("it is immaterial whether patentee correctly understands how his device operates."). [3]

Accordingly, Thorne's proposed definition properly allows the term to be construed in such a way that the public may be on notice of the claim scope and potential for infringement. This is unlike Xymogen's, which incorporates an element of how the oil functions in the human body which would deprive the claim of such notice.

(2) Increasing Volume of a Dosage of CoQ10 Is Critical to the Invention.

The parties additionally depart in determining which aspects, as explained in the '888 patent, are of the greatest importance in construing the claimed composition. Xymogen states that increasing the volume of an individual dosage of CoQ10 "is immaterial to construction" since "of course adding a carrier to the formulation will increase the volume of the dosage." Dkt. No. 55 at p. 10. Instead, the evidence indicates that increasing volume is a critical consideration in formulating the composition.

In the prosecution history of the '888 patent, the inventor stated by declaration "that maintaining a lower concentration of CoQ10, specifically about 50 mg in a size 14 minim capacity (700-900 mg) oblong softgel is critical to maintaining the crystal-free state." Declaration of Donald R. Steele ("Steele Decl.) under Rule 37 C.F.R. § 1.132, Dkt. No. 53-2, p.

[3] Xymogen's construction is also inconsistent with the way that the term "carrier oil" is used in the field of dietary supplementation. For example, many articles about nutritional supplements use the term "carrier oil" to describe oil used as an ingredient in supplements. As it is used in the art, the adjective "carrier" in the term "carrier oil" does not refer to a specific function the oil performs inside of intestinal absorptive cells. Indeed, one definition of a "carrier" is "a usually inactive substance used in association with an active substance especially for aiding in the application of the active substance: as ... b: a vehicle serving especially as a diluent (as for an insecticide or a drug)." Merriam-Webster's Medical Desk Dictionary © 2005 by Merriam-Webster, available at http://www.merriam-webster.com/medical/carrier.

140-149 at p. 144. Also, "the 700-900 mg size is critical in this dose range, since a smaller size would result in a product prone to crystal formation by requiring a higher CoQ10 concentration." The '888 patent describes methods of making a CoQ10 composition that involve mixing the crystal CoQ10, solvent and carrier oil and dissolving the CoQ10 into the solvent. The inventor explains that carrier oil is added to bring the CoQ10 into a concentration range that will reduce the likelihood of crystal formation. Steele Decl., p. 144.

As an additional consideration, "the 700-900 mg size increases the volume of the CoQ10 composition at a desired dosage being presented to the intestinal mucosa, which increases the surface area from which the CoQ10 can be absorbed." Consequently, the volume of the individual dosage that Xymogen alleges "is immaterial to the construction" of the claimed composition accomplishes a dual purpose. The volume both establishes a beneficial concentration range of CoQ10 to maintain its non-crystalline state and increases surface area of an individual dosage, which ultimately influences absorption of the CoQ10. Thus, it is apparent that the volume of carrier oil specifically enables obtaining the 700-900 mg size for the 50 mg CoQ10 dosage discussed by the inventor.

Further, selection of carrier oil volume is a fundamental aspect of configuring the crystal-free coenzyme Q10 composition. While Xymogen states that increasing the volume of the individual dosage is a "tangential effect … immaterial to the construction" of carrier oil (Dkt. No. 55 at p. 10), as considered by the inventor, volume is hardly "tangential" and instead the evidence indicates the inventor viewed it as "critical."

(3) Xymogen's Proposed Construction Is Inconsistent with the Specification and Unsupported.

Finally, unlike Thorne's, Xymogen's construction is inconsistent with the specification. ***Even if*** the carrier oil was to "act[] as a transporter for CoQ10 molecules in the passive facillated

[sic] diffusion process across the absorption cells" ('888 patent, Col. 3, lns. 1-3), it does not necessarily "carr[y] CoQ10 ***across*** absorptive cells in the intestine," as Xymogen urges. Dkt. No. 55 at p. 7 (emphasis added). For example, in the context of molecules entering and passing through the gut epithelial cells (which cover the small and large intestines), the term "facilitated diffusion" refers to how certain types of molecules cross ***cell membranes***, not entire cells. (A cell membrane is the outer layer of a cell.) *See, e.g.*, Exh. C, a textbook excerpt summarizing facilitated diffusion in the context of absorbing molecules from the digestive tract. By rephrasing the role of the carrier oil as "an oil that carries CoQ10 molecules ***across absorptive cells*** in the intestine," Xymogen's definition is inconsistent with the process described in the specification and the literature as it requires that passive facilitated diffusion can carry CoQ10 across cells.

In attempting to support its interpretation of the specification, Xymogen claims that an absorptive cell is like "a security checkpoint" (Dkt. No. 55 at p. 7), pursuant to which "[t]he absorptive cell, the checkpoint, is selective about the types of molecules it will let through the checkpoint and into the blood." *Id.* It adds that "CoQ10 is not one of the molecules that the absorptive cell normally lets into the blood" and "the carrier oil is an [sic] transport vehicle that has clearance to pass through the checkpoint." *Id.*

The problem with this analysis is that it misinterprets the specification's disclosure. Indeed, the part of the specification that Xymogen cites as mentioning that CoQ10 is not normally absorbed in ***blood*** actually is talking about CoQ10 not normally being absorbed into ***the gut epithelial cells***, which Xymogen refers to as the "checkpoint." Specifically, when the patent says that "[w]ithout a lipid carrier the CoQ10 molecules cannot be absorbed," it is referring to absorption from the small and large intestines into the gut epithelial cells. (A

recurrent concept in CoQ10 literature is that CoQ10 is poorly absorbed from the gastrointestinal tract into the gut epithelial cells.[4]). If the CoQ10 is not absorbed into the gut epithelial cells, it will pass through the body and not be absorbed. This is very different, then, than absorption into the blood that Xymogen refers to.

It is unclear what sources Xymogen has for the theory outlined on page 7 of its Brief that a carrier oil transports cells ***across*** absorptive cells, that absorptive cells transmit CoQ10 directly into blood (as opposed to the lymphatic system), or that CoQ10 is a molecule that cells would not ordinarily permit to enter blood. Furthermore, in order to fit with its construction of a carrier oil "carrying" the CoQ10 "across absorptive cells," while Xymogen describes the absorptive cell of its definition as letting CoQ10 pass directly into the blood (Dkt. No. 55 at p. 7); CoQ10 in fact passes into the lymphatic system before passing into the blood.[5]

Since the "facilitated diffusion process" only refers to how certain molecules cross *cell membranes*, and because Xymogen seeks to require that the carrier oil "carr[y] CoQ10 molecules in the passive facilitated diffusion process *across absorptive cells* in the intestine," Xymogen's definition for carrier oil is inconsistent with the patent's specification and the literature.

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[4] *See, e.g.*, Balakrishnan et al., "Enhanced oral bioavailability of Coenzyme Q10 by self-emulsifying drug delivery systems," International Journal of Pharmaceutics 374 (2009) 66–72, attached as Exhibit D.

[5] *See, e.g.*, Bhagavan, "Assessment of coenzyme Q10 absorption using an *in vitro* digestion-Caco-2 cell model," International Journal of Pharmaceutics 333 (2007) 112–117, available at http://www.researchgate.net/publication/6703963_Assessment_of_coenzyme_Q10_absorption_using_an_in_vitro_digestion-Caco-2_cell_model.

CONCLUSION

For the foregoing reasons, Thorne requests that its proposed constructions of the terms "non-crystalline" and "carrier oil" be adopted.

DATED this 15th day of June, 2015.

PARSONS BEHLE & LATIMER

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on the 15th day of June, 2015, I caused the foregoing document to be filed via ECF which provided electronic notice to all counsel of record.

/s/ Kristine E. Johnson
Kristine E. Johnson